Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of acupuncture intervention with pharmacological treatment in improving neck pain and stiffness in patients with cervical spondylosis - clinical trial

Protocol summary

Study aim
Comparative Effectiveness of Oral Pharmacotherapy vs. Acupuncture Intervention in Patients with Cervical Spondylosis: Evaluation of Symptom Severity and Neck Range of Motion

Design
"A phase 3, randomized, open-label, parallel-group, controlled clinical trial conducted on 80 patients."

Settings and conduct
treatment Protocols: Group 1 (Pharmacological Therapy): Patients will receive: Oral piroxicam capsules (10 mg): 1 capsule twice daily (NSAID) Oral methocarbamol tablets (500 mg): 3 tablets (1500 mg) three times daily (muscle relaxant) Treatment duration: 10 days Group 2 (Acupuncture Therapy): Patients will undergo 10 acupuncture sessions over 2 weeks (5 sessions per week). Acupuncture points for cervical spondylosis: SI-3, BL-10, BL-11, BL-14, BL-21, BL-60, LI-4 (for lateral neck pain), LI-17 (for central/posterior pain), DU-14, DU-20, SJ-5, GB-20, GB-21, GB-34, GB-39. Adjunctive Therapies (Both Groups): All patients will be instructed in neck range-of-motion and strengthening exercises. Lifestyle modification education (activity adjustments, posture correction) will be provided. Outcome Assessments: Patients will be evaluated at: Baseline (study initiation) Post-intervention (2 weeks) Follow-ups: 6 weeks and 12 weeks after the last intervention

Participants/Inclusion and exclusion criteria
Inclusion criteria for the study: Patients with cervical spondylosis and osteoarthritis, aged 50 to 80 years, who have experienced neck pain and stiffness symptoms for more than 6 months, will be enrolled in the study after providing written informed consent.

Intervention groups
The first group will receive oral treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and muscle relaxants for 10 days. The second group will undergo 10 sessions of acupuncture therapy over a period of two weeks for treatment.

Main outcome variables
VAS; NDI; Cervical ROM

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250514065735N1**
Registration date: **2025-05-29, 1404/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-29, 1404/03/08**
Update count: **0**

Registration date
2025-05-29, 1404/03/08

Registrant information

Name
Davoud Gholami

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-26, 1404/03/05

Expected recruitment end date
2025-07-27, 1404/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of acupuncture intervention with pharmacological treatment in improving neck pain and stiffness in patients with cervical spondylosis - clinical trial

Public title

Comparison of the effectiveness of acupuncture intervention with pharmacological treatment in improving neck pain and stiffness in patients with cervical spondylosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Signs of Neck Pain and Stiffness Lasting More Than 6 Months

Exclusion criteria:

Clinical signs of effusion, inflammation, redness Rheumatoid arthritis, Inflammatory arthropathy, Fibromyalgia Collagen vascular disease (Lupus), Gout, Cervical disc pathology Trauma, Fracture, Cervical spine surgery History of allergy and Allergic reaction to medications used (NSAIDs and Methocarbamol)

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization in this study will use a permuted block design with a block size of 4. In this method: "A" represents a participant receiving the intervention (acupuncture). "B" represents a participant in the control group (pharmacotherapy). Implementation: All possible 4-sequence permutations (total of 6 combinations) will be used: ABAB BABA AABB BBAA ABBA BAAB Blocks of 4 will be randomly selected to ensure balanced group allocation.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Ethics Committee, Office of Research Affairs 3rd Floor, Building No. 3 School of Medicine, Shiraz University of Medical Sciences Imam Hossein Square, Zand Street Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2025-02-01, 1403/11/13

Ethics committee reference number

IR.SUMS.MED.REC.1403.732

Health conditions studied

1

Description of health condition studied

Cervical spondylosis without myelopathy or radiculopathy

ICD-10 code

M47.812

ICD-10 code description

Cervical spondylosis without myelopathy or radiculopathy

Primary outcomes

1

Description

VAS (Visual Analog Scale) Assessment Protocol: Pain intensity will be evaluated using the Visual Analog Scale (VAS) at the following time points: Baseline (upon study entry)Post-intervention follow-ups: Week 2 Week 6 Week 12

Timepoint

Baseline (upon study entry)Post-intervention follow-ups: Week 2 Week 6 Week 12

Method of measurement

VAS (Visual Analog Scale) Assessment Protocol

2

Description

NDI (Neck Disability Index) Assessment Protocol: The Neck Disability Index (NDI) questionnaire will be used to

evaluate the severity of pain-related disability at the following intervals: Baseline (pre-intervention)Post-treatment follow-ups: Week 2Week 6Week 12

Timepoint

Baseline (pre-intervention)Post-treatment follow-ups: Week 2Week 6Week 12

Method of measurement

NDI (Neck Disability Index) Assessment Protocol

Secondary outcomes

1

Description

Cervical Spine Range of Motion (ROM) Assessment Protocol Measurement Method: Cervical ROM will be quantitatively evaluated using a goniometer at the following time points: Baseline (pre-intervention)Post-intervention follow-ups: Week 2Week 6Week 12

Timepoint

Baseline (pre-intervention)Post-intervention follow-ups: Week 2Week 6Week 12

Method of measurement

goniometer

Intervention groups

1

Description

Intervention group: Pharmacological Treatment Protocol: Piroxicam (NSAID):Dosage: 10 mg oral capsule Frequency: 1 capsule twice daily (BID)Duration: 10 days Methocarbamol (Muscle Relaxant):Dosage: 500 mg oral tablet Frequency: 3 tablets (1500 mg) three times daily (TID)Duration: 10 days

Category

Treatment - Drugs

2

Description

Intervention group: Acupuncture Points for Cervical Spondylosis: Standard Points:SI-3 (Houxi)BL-10 (Tianzhu)BL-11 (Dazhu)BL-14 (Jueyinshu)BL-21 (Weishu)BL-60 (Kunlun)LI-4 (Hegu) – For lateral neck painLI-17 (Tianding) – For central/posterior painDU-14 (Dazhui)DU-20 (Baihui)SJ-5 (Waiguan)GB-20 (Fengchi)GB-21 (Jianjing)GB-34 (Yanglingquan)GB-39 (Xuanzhong)Clinical Rationale: Local Points (e.g., GB-20, BL-10): Target neck stiffness/pain directly. Distal Points (e.g., LI-4, GB-34): Enhance systemic analgesia and Qi flow.DU/GV Points (e.g., DU-14): Regulate Governor Vessel for spinal support.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Emtyaz Hospital

Full name of responsible person

Davoud Gholami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology

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7th Floor, Main Administration Building Shiraz University of Medical Sciences Zand Street

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Davoud Gholami

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available